IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

ELI LILLY AND COMPANY and ICOS CORPORATION, Plaintiffs, v. TEVA PHARMACEUTICALS USA INC. Defendant.	CIVIL ACTION NO. 2:16-cv-519

COMPLAINT

Plaintiffs Eli Lilly and Company ("Lilly") and ICOS Corporation ("ICOS") (collectively "Plaintiffs") file this Complaint for patent infringement against TEVA Pharmaceuticals USA Inc. ("Teva" or "Defendant") under 35 U.S.C. § 271(e)(2) for infringement of U.S. Patent No. 6,943,166 ("the '166 patent").

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Teva. This action relates to Abbreviated New Drug Application No. 090141 ("tadalafil ANDA") submitted by Teva to the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of Lilly's Cialis® (tadalafil) tablets ("proposed tadalafil ANDA product") prior to the expiration of the '166 patent. Teva's tadalafil ANDA includes a "Paragraph IV certification" asserting that the '166 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Teva's proposed tadalafil ANDA product, which constitutes an act of infringement under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2).

THE PARTIES

2. Lilly is an Indiana Corporation that has its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

3. ICOS is a Delaware corporation having its corporate office at Lilly Corporate Center, Indianapolis, Indiana 46825. ICOS is a wholly owned subsidiary of Lilly.

4. On information and belief, Teva is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 425 Privet Road, Horsham, Pennsylvania 19044,.

5. On information and belief, Teva is a pharmaceutical company that formulates, manufactures, packages, and markets generic drug products for distribution in the Eastern District of Virginia and throughout the United States.

6. On information and belief, as stated in its 2015 Annual Report, Teva, together with its related corporate entities, is "the leading generic drug company in the United States."

JURISDICTION AND VENUE

7. Each of the preceding paragraphs 1 to 6 is re-alleged and re-incorporated as if fully set forth herein.

8. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, et seq., and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

10. Teva is subject to personal jurisdiction in this District due, among other things, to its substantial, systematic, purposeful, and continuous contact in this District.

11. Since at least 2007, Teva has maintained an active license with the Virginia Department of Health Professions as a "Non-Resident Wholesale Distributor," which permits Teva to directly distribute prescription drugs to pharmacies, physicians, and other retail entities throughout the Commonwealth of Virginia. On information and belief, pursuant to its Non-Resident Wholesale Distributer license, Teva distributes prescription drugs in this District.

12. One of Teva's principal pharmaceutical manufacturing facilities, employing 428 people is in the Commonwealth of Virginia. The facility is used for warehousing, manufacturing, packaging and distribution of Teva's generic products.

13. Teva is a pharmaceutical vendor for the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) which sells pharmaceuticals in the Eastern District of Virginia and in a number of states. Teva has identified Authorized Distributors of its products, including: national distributors Cardinal Health Inc. and McKesson Corporation, which have facilities in the Eastern District of Virginia, and retail pharmacies CVS Pharmacy Inc., Rite Aid Corporation, Walgreens Co., and Wal-Mart, which have numerous locations in Virginia, including in the Eastern District of Virginia.

14. Teva solicits customers in the Eastern District of Virginia using its extensive website. Through Teva's interactive website, customers and potential customers throughout the United States, including in the Eastern District of Virginia can, among other things: (1) search and download prescribing information for Teva's full product line; (2) sign up to receive alerts when Teva generic products become available; (3) download Teva's Brand-to-Generic Medication

Reference product catalogue; (4) get advice on how to buy Teva products; and (5) download patient materials and health information.

15. Teva consented to personal jurisdiction in the Eastern District of Virginia in other actions. *GD Searle LLC v. Lupin Pharmaceuticals,* Inc., 2:13-cv-00121 (E.D. Va. 2014); *Pfizer Inc. v. Teva Pharmaceuticals USA, Inc.*, 2:10-cv-00128 (E.D. Va. 2011).

16. Teva has also previously availed itself of the benefits of the Eastern District of Virginia Courts by filing suit in this jurisdiction, including, at least, suing GlaxoSmithKline PLC in this court. *Teva Pharmaceuticals v. Glaxosmithkline PLC*, 2:01-cv-00677 (E.D. Va. 2002).

17. Teva is also subject to specific jurisdiction in this District based on the filing of its tadalafil ANDA with a Paragraph IV certification regarding the '166 patent. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

18. As in *Acorda,* Teva "has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at," on information and belief, this District and elsewhere. *Acorda Therapeutics*, 817 F.3d at 759.

19. Teva's "ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." *Acorda Therapeutics*, 817 F.3d at 760.

20. As in *Acorda*, on information and belief Teva "intends to direct sales of its drugs into [Virginia], among other places, once it has the requested FDA approval to market them." *Acorda Therapeutics*, 817 F.3d at 758.

21. On information and belief, Teva will engage in marketing of its proposed tadalafil ANDA product in Virginia, including the Eastern District of Virginia, upon approval of its tadalafil ANDA.

22. Teva's ANDA filing, including its Paragraph IV certifications regarding the '166 patent at issue here, is suit-related, and has a substantial connection with this District because it reliably, non-speculatively predicts activities in this District by Teva.

23. "[T]he minimum-contacts standard is satisfied by the particular actions [Teva] has already taken—its ANDA filing[]—for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in" this District. *Acorda Therapeutics*, 817 F.3d at 760.

24. Exercising personal jurisdiction over Teva in this District would not be unreasonable given Teva's size, contacts in this District, and the interest in this District of resolving disputes related to products to be sold herein.

PATENT-IN-SUIT

25. On September 13, 2005, the U.S. Patent and Trademark Office duly and legally issued the '166 patent entitled "Compositions Comprising Phosphodiesterase Inhibitors for the Treatment of Sexual Dysfunction." A true and correct copy of the '166 patent is attached hereto as Exhibit A. The claims of the '166 patent are valid and enforceable. At the time of its issue, the '166 patent was assigned to Lilly ICOS, LLC and it was subsequently assigned to ICOS which currently holds title.

26. Lilly is the holder of NDA No. 021368 by which FDA granted approval for the marketing and selling of tadalafil tablets in 2.5 mg, 5 mg, 10 mg, and 20 mg dosage strengths for the treatment of erectile dysfunction. Lilly markets tadalafil tablets in the United States under the name "Cialis®" in 2.5 mg, 5 mg, 10 mg, and 20 mg dosage strengths. The '166 patent is one of the patents listed in the FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) as covering the approved indications for Cialis®.

INFRINGEMENT BY DEFENDANT

27. Each of the preceding paragraphs 1 to 26 is re-alleged and re-incorporated as if fully set forth herein.

28. In a letter dated October 17, 2014 ("the Notice Letter"), Teva notified ICOS and Lilly that Teva had submitted its tadalafil ANDA to FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) to obtain approval to engage in the commercial manufacture, use or sale of its proposed tadalafil ANDA product in 2.5 mg, 5 mg, 10 mg, and 20 mg strengths.

29. The Notice Letter states that Teva is seeking approval from FDA to engage in the commercial manufacture, use, and sale of its proposed tadalafil ANDA product before the expiration of the '166 patent. On information and belief, Teva intends to engage in the commercial manufacture, use, and sale of its generic tadalafil tablets after receiving FDA approval to do so.

30. In the Notice Letter, Teva notified Lilly that its tadalafil ANDA contained a Paragraph IV certification asserting that the '166 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Teva's proposed tadalafil ANDA product.

31. Pursuant to 21 U.S.C. 355(j)(2)(B)(ii), any notice letter containing a Paragraph IV certification must contain a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, is unenforceable, or will not be infringed." In Defendant's Notice Letter, Teva does not deny that the commercial manufacture, use, offer to sell, or sale of its proposed tadalafil ANDA product will infringe claims 1, 2, 4-12, if these claims are found valid.

32. Claim 1 of the '166 patent recites "a method of treating sexual dysfunction in a patient in need thereof comprising orally administering one or more unit dose containing about 1 to about 20 mg, up to a maximum total dose of 20 mg per day, of a compound having the structure [that is tadalafil]." Exhibit A, cols. 14-15, line 65-line 15.

33. In its Notice Letter, Teva admits that its proposed tadalafil ANDA product will be orally administered and that it will contain tadalafil as an active ingredient in 2.5 mg, 5 mg, 10 mg, and 20 mg dosage strengths.

34. In its Notice Letter, Teva does not provide any alleged "factual and legal basis" (21 U.S.C. 355(j)(2)(B)(ii)) that its proposed tadalafil ANDA product will not be marketed to treat "sexual dysfunction in a patient in need thereof comprising orally administering one or more unit dose containing about 1 to about 20 mg, up to a maximum total dose of 20 mg per day, of [tadalafil]," consistent with the FDA approved label for Cialis® which states that it is indicated for the treatment of male erectile dysfunction (ED).

35. On information and belief, Teva will market its proposed tadalafil ANDA product to treat "sexual dysfunction in a patient in need thereof comprising orally administering one or more unit dose containing about 1 to about 20 mg, up to a maximum total dose of 20 mg per day, of [tadalafil]," consistent with the FDA approved label for Cialis®.

36. Claim 2 of the '166 patent recites "[t]he method of claim 1 wherein the sexual dysfunction is male erectile dysfunction." Exhibit A, col. 15, lines 16-17.

37. In its Notice Letter, Teva does not provide any alleged "factual and legal basis" (21 U.S.C. 355(j)(2)(B)(ii)) that its proposed tadalafil ANDA product will not be marketed to treat "male erectile dysfunction," consistent with the FDA approved label for Cialis® which states that it is indicated for the treatment of male erectile dysfunction (ED).

38. On information and belief, Teva will market its proposed tadalafil ANDA product to treat male erectile sexual dysfunction, consistent with the FDA approved label for Cialis®.

39. Claim 4 recites "[t]he method of claim 1 wherein the unit dose contains about 2 to about 20 mg of the compound." Exhibit A, col. 15, lines 20-21. In its Notice Letter, Teva admits that its proposed tadalafil ANDA product will contain tadalafil as an active ingredient in 2.5 mg, 5 mg, 10 mg, and 20 mg dosage strengths.

40. Claim 5 recites "[t]he method of claim 1 wherein the unit dose contains about 5 mg of the compound. Exhibit A, col. 16, lines 3-4. In its Notice Letter, Teva admits that its proposed tadalafil ANDA product will contain tadalafil as an active ingredient in a 5 mg dosage strength, among others.

41. Claim 6 recites "[t]he method of claim 1 wherein the unit dose contains about 10 mg of the compound and is administered once per day." Exhibit A, col. 16, lines 5-7. In its Notice Letter, Teva admits that its proposed tadalafil ANDA product will contain tadalafil as an active ingredient in a 10 mg dosage strength, among others.

42. In its Notice Letter, Teva does not provide any alleged "factual and legal basis" (21 U.S.C. 355(j)(2)(B)(ii)) that its proposed tadalafil ANDA product will not be marketed to be "administered once per day," consistent with the FDA approved label for Cialis®.

43. On information and belief, Teva will market its proposed tadalafil ANDA product for once daily use, consistent with the FDA approved label for Cialis®.

44. Claim 7 recites "[t]he method of claim 1 wherein the unit dose is in a form selected from the group consisting of a liquid, a tablet, a capsule, and a gelcap." Exhibit A, col. 16, lines 8-9. In its Notice Letter, Teva admits that its proposed tadalafil ANDA product is a tablet product.

45. Claim 8 recites "the method of claim 1 wherein the unit dose contains about 2.5 mg of the compound." Exhibit A, col. 16, lines 11-12. In its Notice Letter, Teva admits that its proposed tadalafil ANDA product will contain tadalafil as an active ingredient in a 2.5 mg dosage strength, among others.

46. Claim 9 recites "[t]he method of claim 8 wherein the unit dose is administered once per day." Exhibit A, col. 16, lines 13-14.

47. In its Notice Letter, Teva does not provide any alleged "factual and legal basis" (21 U.S.C. 355(j)(2)(B)(ii)) that its proposed tadalafil ANDA product will not be marketed to be "administered once per day," consistent with the FDA approved label for Cialis®. On information and belief, Teva will market its proposed tadalafil ANDA product for once daily use, consistent with the FDA approved label for Cialis®.

48. Claim 10 recites "[t]he method of claim 5 wherein the unit dose is administered once per day." Exhibit A, col. 16, lines 13-14.

49. In its Notice Letter, Teva does not provide any alleged "factual and legal basis" (21 U.S.C. 355(j)(2)(B)(ii)) that its proposed tadalafil ANDA product will not be marketed to be "administered once per day," consistent with the FDA approved label for Cialis®. On information and belief, Teva will market its proposed tadalafil ANDA product for once daily use, consistent with the FDA approved label for Cialis®.

50. Claim 11 recites "[t]he method of claim 1 wherein the compound is administered as a free drug." Exhibit A, col 16, 15-16.

51. In its Notice Letter, Teva does not provide any alleged "factual and legal basis" (21 U.S.C. 355(j)(2)(B)(ii)) that its proposed tadalafil ANDA product will not be "administered as a

free drug." On information and belief, Teva's proposed tadalafil ANDA product will contain tadalafil as a free drug.

52. Claim 12 recites "[t]he method of claim 1 wherein the unit dose contains about 20 mg of the compound." In its Notice Letter, Teva admits that its proposed tadalafil ANDA product will contain tadalafil as an active ingredient in a 20 mg dosage strength, among others.

COUNT I: INFRINGEMENT OF THE '166 PATENT UNDER 35 U.S.C. § 271(e)(2)(A)

53. Each of the preceding paragraphs 1 to 52 is re-alleged and re-incorporated as if fully set forth herein.

54. Defendant's submission of its tadalafil ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of its proposed tadalafil ANDA product prior to the expiration of the '166 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

55. On information and belief, upon FDA approval of Defendant's tadalafil ANDA, Defendant will infringe at least one claim of the '166 patent by making, using, offering to sell, and selling its proposed tadalafil ANDA product in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c) unless enjoined by the Court.

56. If Defendant's marketing and sale of its proposed tadalafil ANDA product prior to expiration of the '166 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

Wherefore, Plaintiffs demand judgment against Defendant and respectfully request that this Court grant the following relief:

A. A judgment that the claims of the '166 patent are not invalid, not unenforceable, and are infringed by Defendant's submission of its tadalafil ANDA, and that Defendant's making, using, offering to sell, or selling in the United States, or importing into the United States Defendant's proposed tadalafil ANDA product will infringe the '166 patent.

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Defendant's tadalafil ANDA shall be a date which is not earlier than the latest expiration date of the '166 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

C. An order permanently enjoining Defendant, its affiliates, subsidiaries, and each of its officers, agents, servants and employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States, Defendant's proposed tadalafil ANDA product until after the latest expiration date of the '166 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

D. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: September 2, 2016

Respectfully submitted,

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